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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/070,707	07/10/2002	Borje Rantala	2534-00068	7588

26753 7590 12/15/2004

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EXAMINER

SCHAETZLE, KENNEDY

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 12/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/070,707

Applicant(s)

RANTALA ET AL.

Examiner

Kennedy Schaetzle

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 March 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. ____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 7/10/02, 10/31/02.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Specification

1. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

Claim Objections

2. Claims 1, 3-5 and 12 are objected to.

In claim 1, the steps associated with the method must be clearly and positively set forth in a present tense format in order to make it clear what steps are actually being performed. The examiner will assume it was the applicants' intent to recite a method comprising measuring the electrical activity of a patient by means of a single piece of equipment, wherein the step of measuring includes the step of taking a 5-lead electrocardiogram, etc.

Antecedent basis for "...the selector switch..." in claims 3-5 has not been provided. The reference to positions I, II and III are also vague, as the applicants have not set forth the use of a selector switch with such positions. The examiner will assume it was the applicants' intent to recite the provision of a selector switch with three positions.

In claim 12, the attachment of electrodes to the patient should be referred to in a functional sense (e.g., "...electrodes adapted to be attached to the patient...") in order to make it clear that the body is not being claimed as a part of the invention.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claim 6 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not

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described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The limitation regarding changing the channels to "...a bigger amplification..." was not originally disclosed (the original specification referred to "...a bigger resistance...").

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Swenson et al. (Pat. No. 5,623,925).

Regarding claim 1, Swenson et al. disclose a method for a medical monitoring system in which the changes in the electric activity of a patient are observed and the functions of a patient are measured. The method includes the step of measuring the electrical activity of a patient under the direction of two or more diagnostic test protocols taken by means of one piece of measuring equipment (note for example col. 1, line 58-col. 2, line 8). Such tests include 12-lead ECG and EEG measurements. Although 5-lead ECG and IKG tests are not explicitly discussed, it would have been readily apparent from the disclosure of Swenson et al. that any number of diagnostic tests from the plethora of known tests available could have been employed in the practice of the Swenson et al. method. The type and number of tests performed is clearly not critical to the Swenson et al. invention as the main goal is to provide a testing machine that eliminates the need for separate, dedicated testing apparatus. Clearly the types of diagnostic tests associated with the method would depend upon the condition of the individual under treatment, with the decision residing with the physician responsible for the care and treatment of the patient. To include a 5-lead ECG and/or an IKG test as

needed would have therefore been considered blatantly obvious by those of ordinary skill in the art.

Regarding claim 2, the examiner takes Official Notice that the use of 10 conductors is standard in any 12-lead ECG test. Swenson et al. teach that multiple tests may be conducted with a common set of conductors (note for example col. 7, lines 28-36), with the conductor configuration being selected based on the measurement (note col. 2, lines 54-57).

Regarding claims 3-5, although Swenson et al. do not discuss a selector switch turned to any particular position, they do teach the need for a selector switch as per col. 2, lines 50-57, with the suggestion that the selector can be a computer keyboard, mouse or touch screen (col. 4, lines 48-58). The particular form that the switch takes is clearly immaterial to the invention. It makes no difference whether one employs a three position rotary switch or a computer touch screen as long as the option of selecting is made available to the operator.

Regarding claim 6, as best as can be understood, the examiner will consider the preamplifier in the receiving means of Swenson et al. to be a "control type device" that changes the EEG channels to a "bigger amplification."

Regarding claim 7, whether one desires to monitor the EMG of the facial muscles or not is purely a physician's prerogative depending on the condition of the patient and the prescribed treatment. A related comment applies to claim 8.

Regarding claim 9, Swenson et al. teach that it is a matter of design whether or not one desires to use the same electrode for different tests (note col. 7, lines 28-36). To utilize the same neutral electrode for both EEG and ECG channels would have therefore been considered blatantly obvious to any artisan of ordinary skill.

Regarding claim 10, Swenson et al. suggest testing the electrodes in order to ensure proper connection (note col. 9, lines 1-21). While the use of an impedance test is not explicitly mentioned, the examiner takes Official Notice that it is old and well-known in the electrode art to monitor the state of electrode configurations by detecting an impedance signal associated therewith. To use such a ubiquitous and suitable test

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would have therefore been considered a matter of obvious design by those of ordinary skill in the art.

Regarding claim 11, again the examiner reiterates that the particular ECG tests performed, whether they be a 12-lead, a 5-lead, a 3-lead and/or a 2-lead measurement, relies upon the shoulders of the physician under whose care the patient depends. To utilize whatever test is necessary for proper patient care would have therefore been considered an obvious physician prerogative by those of ordinary skill in the diagnostic arts.

Regarding claim 12, note the comments made in the rejection of claim 1 and claims with similar limitations above.

Regarding claim 13, the preamplifier unit of Swenson et al. is considered capable of utilization in the manner set forth.

Concerning claim 14, note the comments made in the rejection of similarly worded claim 10.

Regarding claim 15, comments paralleling those made in the rejection of claim 1 apply here as well.

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

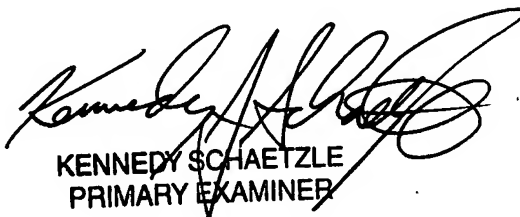
8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kennedy Schaetzle whose telephone number is 571 272-4954. The examiner can normally be reached on M-W and F from 9:30 -6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on M-F at 571 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KJS
December 10, 2004



KENNEDY SCHAETZLE
PRIMARY EXAMINER